**Part 3 – Description (Revised)**

The following is a description of the requirements under this service contract.

## A. Project Administration

### 1. Meeting Management

Scope:

a) The contractor shall schedule and host bi-weekly CDER/CBER Empirica Signal status meetings (via teleconference) with a maximum duration of 1 hour. The contractor shall draft and store the meeting minutes in the CDER Data Mining Projects SharePoint Site (SPS).

b) The contractor shall schedule and host separate monthly CBER-focused Empirica Signal status meetings (via teleconference) with a maximum duration of 1 hour. The contractor shall draft and email the meeting minutes.

Project Assumptions:

a) For bi-weekly CDER/CBER Empirica Signal status meetings, FDA participants will include core members of the CDER/CBER data mining team. For the monthly CBER-focused Empirica Signal status meetings FDA participants will include core members of the CBER data mining team.

### 2. Status Reports

Scope:

a) The contractor shall prepare and deliver separate monthly status reports to CDER and CBER. The reports will detail deliverables, data and Signal Management refreshes, infrastructure status, pending/future service activities, support issues, and product name mapping and Signal Management modifications during the reporting period.

b) The contractor shall store the CDER status reports in the CDER Data Mining Projects SPS and email the reports to the CBER team.

Project Assumptions:

a) The status reports will be delivered by the seventh day of the following month.

## B. Operations & Maintenance

### 1. Data (Database) Administration

Scope:

a) The contractor shall provide Empirica Signal related database and application operations and maintenance services to ensure the availability of Empirica Signal to CDER and CBER users. Database administration services will include server issue identification, analysis and appropriate resolution in the Empirica Signal production environment.

b) The contractor shall coordinate with the FDA OIM DBA to follow established OIM processes in the Empirica production environment.

### 2. Data, Standard Runs and Signal Management Refresh

Scope:

a) The contractor shall perform standard data preparation activities including data ETL (Extract-Transform-Load), validation, error checking, time stamping, product name standardization/coding. MedDRA updates will be implemented when event terms from the latest MedDRA version appear in the FAERS/CBAERS or VAERS data. The contractor shall confirm that the data preparation process has been executed.

b) Following the data preparation activities, the contractor shall refresh the FAERS/CBAERS and CBER VAERS data and standard runs (19 FAERS runs and 16 VAERS runs) on a weekly basis and the FAERS and VAERS Signal Management runs and views on a monthly basis.

Government Obligations:

a) The FDA will be responsible for providing FAERS/CBAERS and VAERS data extracts for the contractor to load and process the data.

b) Additional drugs or vaccines to be incorporated into Signal Management will be supplied by CDER or CBER, respectively.

### 3. Product Name Data Management

Scope:

a) The contractor shall map product name verbatims to the appropriate generic and trade name in accordance with the existing mapping standardization process, maintain product name standardization to account for corrections, concatenated terms, custom terms, and product categories, and maintain the corresponding data dictionaries.

b) The contractor shall perform product name mapping updates on a monthly basis, coordinated with the Signal Management refresh processes.

Government Obligations:

a) CDER will be responsible for providing newly FDA-approved drug names for mapping and the contractor shall conduct the verbatim mapping and incorporation into Signal Management, where appropriate.

b) CBER may provide guidance into the appropriate mapping of therapeutic biologics.

## C. Ad-hoc Consulting Assistance

### 1. Consulting Assistance

Scope:

a) The contractor shall provide up to five (5) person days of consulting assistance to address Empirica Signal "ad hoc" requests. The assistance may include performing the following activities:

1. Performing Signal Management reviewer assignments in the Empirica Signal application (to minimize the time to execute this activity, the contractor shall advise that the requestor specifies the standard drug name currently in Signal Management, where appropriate, as opposed to the drug name from the FAERS product assignment list).

2. Other requests that may be captured under this category include assistance with data mining runs, reports, queries or other Empirica Signal functionalities.